DCFS Weekly Update From the State Office

Monday, June 11, 2001

Budget Woes Again--This Time We're Not Alone!

By Richard J. Anderson

If you've read the newspapers over the past couple of weeks, I'm sure you're aware of the decrease in state revenue predicted for next year. The decrease in profits from the stock market and commensurate decreases in income taxes were the two major factors. Each department in state government was asked to place a hold on some expenditures until there is a better fix on how much there will be in lost revenue. We will know more later in the summer and into the fall. The measures being put in place across state government are precautionary, although most think that the plans to place things on hold will, most likely, mean decreases in overall budgets. Each division presented possible areas to hold back. We will know by next week which ones the division will be holding. **The good news is that your raises and the discretionary increases for next year have not been touched.** Also, we may have a safety valve funding source that can help our division through this period.

Following are some of the directives effective immediately within the Department of Human Services (DHS) as issued by our Department Executive Director, Robin Arnold-Williams:

- Approval from the Executive Director's Office will be required prior to recruiting and filling any staff vacancy at the state office level of any DHS division or office. This does not apply to vacancies at the regional or institutional levels.
- Approval from the Executive Director's Office will be required prior to the purchase of any computer hardware, including printers.
- Approval from the Executive Director's Office will be required prior to scheduling or conducting any staff training, conferences, or retreats where expenditures will exceed $500 total.
- Approval from the Executive Director's Office will be required for all out-of-state travel. Travel related to client needs (e.g., DYC and DCFS pick up or drop off of children/youth) which requires short turn-around time can be handled via phone or e-mail approvals. All non-client related out-of-state travel will be limited to national meetings/conferences where staff are in leadership positions, necessary meetings with federal officials, meetings/conferences where costs are being reimbursed by another entity, and meetings/conferences where attendance is mandated. In all cases, travel to any one event will be limited to no more than one traveler. Exceptions to these parameters may be granted on an individual case basis with sufficient justification.

If the revenue picture improves over the coming months, one or more of these directives may be lifted. We will be notified as changes occur.

Stay tuned. Don't panic. I think we will make it through the state deficit projections easier than the last budget adjustments we experienced.

My Response to the Weekly Update--Special Edition of May 21, 2001

By Rachel Gehring, Fostering Healthy Children

I really enjoy reading the Weekly Update. You do a great job. I find it very informative and I enjoy knowing about the changes at DCFS.

I especially enjoyed Richard Anderson's compliments and encouragement to the hard working and caring CPS workers. They seem to be in the line of fire at all times. I understand their frustrations and they deserve to be validated and encouraged for doing a good job.

My daughter-in-law worked for DCFS, after graduating with her Master's Degree from the University of Utah. She loved her work; however, because of the constant pressure from within the system, she chose to be a part of the 50 percent turnover. She left a job she loved and has moved on.

I would like to take a moment to mention an article in the *Salt Lake Tribune*, May 23, 2001, featuring Natalie Williams and the adoption of her two nine-month-old twins. The story truly hit a soft spot in my heart. Just think: a single mom, professional basketball player, and making time for motherhood for two beautiful adopted twin babies.

I am a secretary at Fostering Healthy Children. I see so much sadness passing by my desk, of hundreds of unwanted and abused children in need of being adopted. Sometimes the sadness for these Utah children is overwhelming. Then I get the privilege to read the story about Natalie Williams in the *Salt Lake Tribune*. This great lady and awesome athlete generates renewed hope for humanity and the children in Utah. Natalie is truly a shining Utah Star (Starrz) and mother.

(If you would like to read the article referenced above, click on the following link: http://www.sltrib.com/2001/may/05232001/utah/99654.htm.)

Interested in Research? Read On…

By Navina Forsythe

If you are a DCFS employee or outside agency interested in doing research involving DCFS clients or data, you may need to submit a proposal to the Department of Human Services Protection of Human Rights Review Committee (PHRRC). This committee serves as the Institutional Review Board for the Department. Federal regulations define "research" as "*a systematic investigation…designed to develop or contribute to generalizable knowledge.*" This may include surveys, or reviewing data that DCFS currently stores on its clients. Any research involving human subjects in this way needs to be reviewed. Human subjects may be clients, caseworkers, foster parents, or providers.

If you are a Department employee and your study activity involves human subjects and constitutes "research" as defined above, you must submit your research proposal

to the appropriate Division representative for review and you must obtain prior written approval from that Division before any client contact is made.

If you are not a Department employee and you want to conduct a study using Department clients or data, you must first submit your proposal to the appropriate Division representative. If the Division approves the proposed research, it will forward the research proposal and a letter of endorsement to the Human Rights Committee for its review.

Attached are the Department Policies regarding research, including a flowchart to determine if you need to submit a proposal to the PHRRC or just to the Division. I am the DCFS representative on this committee. If you have any questions about this process please contact me via email or by phone (801) 538-4045.

Once research is completed the final report is submitted to the Division so that the findings can be utilized.

DEPARTMENT OF HUMAN SERVICES POLICY AND RESOURCE MANUAL	
Department of Human Services	Page 1 of 1
Reference: 01-10	Effective date: February 21, 2000
Subject: PROTECTING THE RIGHTS OF HUMAN RESEARCH SUBJECTS POLICY AND PROCEDURES	
RATIONALE: The Utah Department of Human Services (the "Department") is supportive of quality research, especially when such research provides additional insights into the Department's client populations and improves the Department's services. The Department seeks, however, to protect the safety and privacy of any human subjects involved in these research projects. This policy and procedures are intended to assist the Department in reviewing research proposals and protecting individual rights, and complying with federal laws governing research with human subjects.	

POLICY ABOUT RESEARCH INVOLVING HUMAN SUBJECTS

It is the Department's policy that any research involving human subjects (including the Department's clients, clients' family members, clients' victims, or employees) shall comply with the following rules and policies: (1) federal regulations about human-subjects research (45 CFR Part 46); (2) the Department's Vision and Mission Statements; (3) the Department's Code of Ethics; and (4) the policies and procedures contained in this document. To assure that these requirements are met, all research proposals and protocols must be reviewed by an appropriate authority within the Department. That is, depending on the nature and source of the proposed research, the proposal must be reviewed by either: (1) the appropriate Division director (or the director's designee); or (2) the appropriate Division Director (or the director designee) and the Department's Protection of Human Rights Review Committee ("Human Rights Committee") and the Department's Deputy Director. If the proposed research involves pharmaceuticals or bio-medical devices, additional review requirements must be met. The attached Procedures and Instructions provide details about the kind of review required for specific types of research.

These procedures and instructions must be followed ***before*** the researcher begins any research involving human subjects. In addition, if a researcher proposes to change any research design, procedures or instruments previously approved by the Human Rights Committee, the researcher must secure approval for such changes ***before*** implementing them. Ongoing research must be reviewed by the appropriate authority at least once a year.

_____ DATE 02-21-00

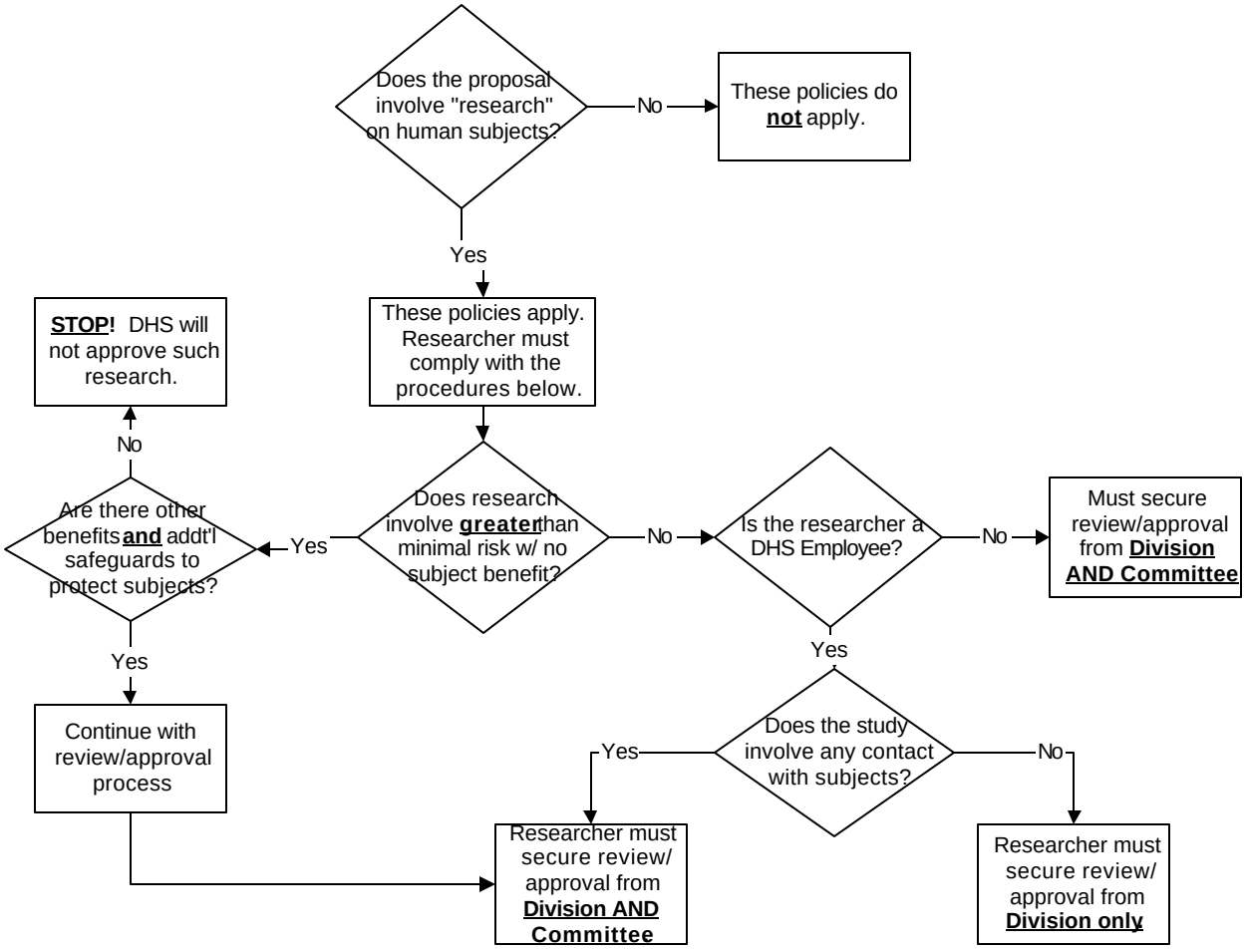
Robin Arnold-Williams, Executive Director
Utah Department of Human Services

UTAH STATE DEPARTMENT OF HUMAN SERVICES
Protection of Human Rights Review
PROCEDURES AND INSTRUCTIONS

INTRODUCTION AND OVERVIEW.

The Human Rights Committee serves as the Institutional Review Board ("IRB") for the Department. Except as otherwise provided below, the Human Rights Committee reviews all proposed research and research methodologies relating to Department clients, staff, contractors, or any other human subjects involved with the Department.

Please note, however, that these policies and procedures apply only to "research" activities involving human subjects. The next section—entitled "How to Determine Whether a Project Qualifies As Research"—explains in more detail which studies are considered to be "research." In addition, the following flow-chart gives an overview of the decision-making process for determining which type of review is appropriate for a particular research project.



HOW TO DETERMINE WHETHER A PROJECT QUALIFIES AS "RESEARCH" INVOLVING HUMAN SUBJECTS.

These policies and procedures apply only to "research" activities that involve human subjects. Federal regulations define "research" as "*a systematic investigation*, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge*. Activities which meet this definition constitute research for purposes of this policy [of protecting human subjects], whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." 45 CFR § 46.102(d) (emphasis added). In other words, the label attached to the activity is not the determinative factor; a research study does not cease to be research simply because it is labeled as "treatment" or "program evaluation."

This means that as a general rule, the following activities do not qualify as "research" *when conducted by Department employees*: reviewing client records in order to respond to a client's complaint; providing standard treatment to a client; or undertaking routine statistical tabulations and program audits for administrative purposes only. Because these activities are not "research" but are part of the usual job activities for Department employees, they do not require approval from either the Human Rights Committee or from the Division.

As explained in the "Scope of Review" section below, however, Department employees who engage in "research" involving human subjects <u>do</u> need to submit their research proposals for approval. Department employees who are unsure whether their proposed research must be approved by the Human Rights Committee, or the Division, or whether the proposed research falls into one of the non-research categories described above should contact the Chairperson of the Human Rights Committee at (801) 538-4295. If after consulting with the Chairperson, the employee still has questions about whether the project needs to be reviewed, it is wisest to submit the full proposal to the Human Rights Committee.

As a minimum the Department Human Rights Committee reviews the proposed research to determine that the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The Human Rights Committee reviews only those research studies that involve *human* subjects. Other types of research may need approval from the Division or the Department, but these policies do not apply.

SCOPE OF REVIEW, BASED ON THE TYPE OF PROPOSED RESEARCH.

The scope of review depends, in part, on whether the research is conducted by a Department employee or by someone other than a Department employee. The scope of review also depends on the level of risk involved for the human subject, and whether the study involves pharmaceuticals or biomedical devices. Each of these factors is discussed in more detail below.

Studies Conducted by Department Employees

If you are a Department employee and your study activity involves human subjects and constitutes "research" as defined above, you must submit your research proposal to the appropriate Division representative for review and you must obtain prior written approval from that Division before any client contact is made. (For more information about the review process, please refer to the section titled "Divisions As Gatekeepers" below.)

*For many research studies, the Department employee must also obtain prior written approval from the Human Rights Committee. (*Please see the section below on "Mandatory Review Categories.")

Studies Conducted by Researchers Who Are NOT Department Employees

If you are not a Department employee and you want to conduct a study using Department clients or data, you must first submit your proposal to the appropriate Division representative. (See "Instructions for Obtaining Human Rights Approval," page 11 below.) If the Division approves the proposed research, it will forward the research proposal and a letter of endorsement to the Human Rights Committee for its review.

Studies Involving Pharmaceuticals or Biomedical Devices

Regardless of whether the researcher is a Department employee or an outside researcher, any research which involves the use of pharmaceuticals or biomedical devices with human

subjects must be reviewed by both the Division and the Human Rights Committee, and the researcher must satisfy additional requirements. The researcher should contact the Chairperson of the Human Rights Committee for more detailed information concerning those requirements.

Phase I or II studies involving investigational pharmaceutical drugs or biomedical devices are prohibited. See Appendix A for definitions of the terms "Phase I," "Phase II" and "Phase III."

RESEARCH RISKS AND LEVELS OF REVIEW

The Divisions and the Human Rights Committee will use the following risk categories to determine the appropriate level of review:

1. **"Low-Risk" Research (Less Than "Minimal Risk")**. This category refers to research in which the researcher will not contact the human subject in person, but may request access to client data maintained by the Department or its contractors, and the risk of harm or discomfort to the human subject is less than minimal. (Please refer to the next category for a definition of "minimal risk.") The following research may be considered "low-risk": (a) the researcher reviews client data, databases or aggregate data that contain no information by which an individual subject can be identified; or (b) the researcher reviews client data or databases that contain the clients' names or other identifying information.

Review requirements for "Low-Risk" Research. Research in the "low-risk" category is exempt from Human Rights Committee review *if the research is conducted by a Department employee*. Nevertheless, all "low-risk" research requires Division approval and assurances that the researcher has made adequate provisions to safeguard data and to comply with *Utah Code Annotated* § 63-2-202(8), which specifies when the Department may allow access to "private" or "controlled" records for research purposes. The Division may delegate such review and approval authority to its Regional Directors as long as the Regional Directors comply with this policy and determine that the researcher has made adequate provisions to safeguard data. If the "low-risk" research is conducted by an outside researcher (i.e., someone other than a Department employee), the research proposal needs to be approved by both the Division and the Human Rights Committee.

2. **"Minimal Risk"[1] Research**. This category refers to research that involves *interaction* with the human subject when the probability and magnitude of harm or discomfort that the researcher anticipates will be experienced by the human subjects are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Review requirements for "Minimal Risk" Research. All research in this category requires Human Rights Committee review, and prior *review of methodology* and letter of support from the appropriate Division Gatekeeper, regardless of whether the research is conducted by a Department employee or an outside researcher. The researcher must

[1] According to 45 CFR § 46.102 (i), "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

assure that informed consent and informed assent (where applicable) requirements are met. (See "Informed Consent" checklist on page 18 below.)

3. **Research Involving Greater Than Minimal Risk to the Human Subjects, But Providing Some Direct Benefit to the Subjects**. This category refers to research that involves *intervention/interaction* with the human subject for treatment or survey purposes when the subject's anticipated harm or discomfort involves a greater-than-minimal risk* and when the intervention presents the prospect of direct benefit to the individual subject.

Review requirements. All research in the "greater-than-minimal risk" category requires Human Rights Committee review, and prior *review of methodology* and letter of support from the appropriate Division Gatekeeper. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (See "Informed Consent" checklist on page 18 below.) The Human Rights Committee may approve research involving a greater-than-minimal risk **only if** its review finds that:

(a) the proposed intervention or procedure holds out the prospect of direct benefit for the individual subject, or the intervention or procedure involves a monitoring procedure that is likely to contribute to the subject's well-being;

(b) The risk is justified by the anticipated benefit to the human subjects;

(c) The relation of the anticipated benefit to the risk is at least as favorable to the human subjects as that presented by available alternative approaches; and

(d) The researcher has made adequate provisions for soliciting informed consent of human subjects, and the informed assent of children and permission of their parents or guardians as set forth in 45 CFR § 46.408.

4. **Research Involving "Greater-Than-Minimal Risk" and No Direct Benefit to the Human Subjects, but Likely to Yield Generalizable Knowledge about the Subject's Disorder or Condition**. This category refers to research that involves a greater-than-minimal risk (see definition of "minimal risk" above) by an intervention or procedure that does not hold out the prospect of direct benefit to the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, but is likely to yield generalizable knowledge about the subject's disorder, condition, or the programs designed to assist or ameliorate the subject's disorder or condition.

Review requirements. All research in the "greater-than-minimal risk" with no direct benefit to subject category requires Human Rights Committee review, and prior *review of methodology* and letter of support from the appropriate Division Gatekeeper. The researcher must assure that informed consent requirements are met and that where applicable, informed assent requirements for children are met. (See "Informed Consent" checklist on page 18 below.) The Human Rights Committee may approve research in this category **only if** its review finds that:

(a) the risk represents a minor increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition or for the understanding of the programs designed to ameliorate the subjects' disorder or condition;

(d) the generalizable and/or program benefits outweigh the risks to subjects; and

(e) The researcher has made adequate provisions for soliciting informed consent of human subjects, and the informed assent of children and permission of their parents or guardians as set forth in 45 CFR § 46.408.

Studies Involving Greater- Than-Minimal Risk, with No Benefit to the Human Subject, nor Generalizable or Program Knowledge.

If the proposed research study involves more than minimal risk to the human subject, with no prospect of direct benefit to the individual subjects, and the study is not likely to yield generalizable knowledge about the subject's disorder or condition or the programs designed to serve the subject population, the **Department will not review or approve the study, regardless of whether the researcher is a Department employee or an outside researcher**.

5. **Research Involving Pharmaceutical or Biomedical Devices**. If a research proposal involves pharmaceuticals or biomedical devices, the researcher must satisfy additional requirements. The researcher is directed to contact the Chairperson of the Human Rights Committee for specific information concerning those requirements.

Phase I or II studies involving investigational pharmaceutical drugs or biomedical devices are prohibited. See Appendix A for definitions of the terms "Phase I," "Phase II" and "Phase III."

DIVISIONS AS "GATEKEEPERS" IN THE REVIEW PROCESS.

Each Division in the Department shall designate a representative to serve on the Human Rights Committee and to serve as a "gatekeeper" to review any proposed research study that involves the Division's clients or resources. Each research proposal must be reviewed by the gatekeeper of the appropriate Division, regardless of whether the research must also be reviewed later by the Human Rights Committee. The Division's "gatekeeper" shall review the proposed research and make written findings that indicate whether:

(a) the research is in the best interests of the Division and the Division's clients;

(b) the researcher has made adequate provision for obtaining informed consent from the subjects or the subjects' parents or legal guardian, and where applicable, informed assent from children or clients who suffer from some mental incapacity;

(c) the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the researcher's gathering of the data, storage and retrieval of the data, and publication of the data,

(d) the research study involves no more than minimal risk to subjects, or if the risk is more than minimal, that the direct benefits to the human subjects outweigh the risks (see definition of "minimal risk" on page 4);

(e) the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department or the Division; and,

(f) the research protocol protects individual privacy rights, and complies with the Department's Vision and Mission Statements, the Department Code of Ethics and any applicable rules or statutes, including *Utah Code Annotated* § 63-2-202(8) (GRAMA).

If the Division representative finds that the proposed research satisfies these requirements, the representative shall prepare a written statement to this effect, and shall submit this statement to the Division director for written approval. If the Division director approves the research project, the Division's representative shall send a copy of the representative's written findings and the Director's approval to the Human Rights Committee.

If the proposed research also requires the review and approval of the Human Rights Committee, the representative shall also notify the Human Rights Committee of this requirement, and shall forward the researcher's application and supporting documentation to the Human Rights Committee for its review. If the research involves greater-than-minimal risk but no direct benefit to the human subjects, the Division representative shall notify the researcher and the Human Rights Committee in writing why the research does or does not qualify for approval under the section of these policies that deals with such studies.

RESEARCH THAT NEEDS TO BE REVIEWED ONLY BY THE DIVISION.

If a *Department employee* proposes to engage in the following research activities, the employee must secure prior approval from the appropriate Division(s), but review by the Human Rights Committee is *not* required unless the research also falls into one of the "mandatory review" categories listed in the next section:

(a) Research that involves the review of existing case logs or other client-identifiable records maintained by the Department or a Division if:

(1) the employee normally has access to such logs or records to carry out his or her job responsibilities, or

(2) the employee does not normally have access to such logs or records, but the director of the Division which maintains such logs or records has reviewed the proposed research and has authorized the employee to have access for that purpose;

(b) Conducting client-satisfaction surveys or administering similar questionnaires to the Department's clients and their families, or to the Department's consumers, contract providers or collateral contacts, as long as:

(1) the questions focus on programs or services provided by the Department or a Division;

(2) the questions do not intrude on the survey respondent's personal privacy by asking for information (such as sexual history or substance-abuse history) of the kind that most respondents would prefer to keep confidential; *and*

(3) the survey or questionnaire is administered only to clients who can make an informed choice about whether to participate in the survey or study. (For example, some individuals in the following categories may be *unable* to make such an informed choice and may need the consent of parents, guardians and/or treating physicians: children; clients who are mentally incompetent; clients whose developmental disabilities or serious mental illnesses appear to impair their judgment about whether to participate in the study.)

(c) Conducting routine quality assurance reviews or audits for the Department or Division.

By way of further example, Department employees do not need Human Rights Committee approval for the following routine activities: research studies involving the analysis of existing records or information normally maintained as part of the agency's services or functions; needs-assessment studies; customer/employee satisfaction surveys; service delivery assessments; in-house program evaluations or audits; and interviews/surveys of clients, employees, contract providers or service partners such as the courts.

As noted above, however, prior approval for such research studies is always required from the Division itself. In addition, any research done by an "outside researcher" (i.e., a researcher who is not a Department employee) requires review and approval by both the Division and the Human Rights Committee, even if that research is the type discussed in this section.

"MANDATORY HUMAN RIGHTS COMMITTEE REVIEW" CATEGORIES.

Prior review and approval by both the Division and the Human Rights Committee is required before a researcher (including a Department employee) may conduct any of the following types of research studies or before the researcher may contact the Department's clients or subjects:

(a) ***Research Involving More-Than-Minimal Risk to Human Subjects.*** Review by the Human Rights Committee is required for any research that poses more than minimal risk to clients or their families, regardless of whether the research is conducted by Department employees or others.

(b) ***Federally-Funded Research.*** Review by the Human Rights Committee is required for *all* federally-funded research, regardless of whether the research is conducted by Department employees or others.

(c) ***Research by Individuals and Agencies Outside the Department.*** Review by the Human Rights Committee is required for *all* research by individuals or agencies

outside the Department if the researcher is requesting or gaining access to Department data or Department clients for research studies. (Please note that if the researcher is outside the Department, the Human Rights Committee's review is required regardless of whether the Department or a Department agency has requested or contracted for outside assistance in the study, and regardless of whether the study involves Department clients served by private contract providers. In other words, companies and individuals that contract with the Department to provide services to the Department's clients and consumers are considered to be "outside the Department.")

(d) ***Non-Routine Research by Department Employees.*** Review by the Human Rights Committee is required for any research studies prepared and conducted by Department employees if the research involves human subjects (including the Department's clients or their families) *and* the research is outside the scope of the employees' usual case management activities or quality assurance activities.

(1) By way of example, review by the Human Rights Committee *is* required if a Department employee proposes to conduct the following research studies:

(A) Pharmaceutical research or research about biomedical devices;

(B) Research involving any invasive or painful medical or therapeutic procedures, including blood draws;

(C) Research that compares the efficacies of certain therapies, *and* involves the use of control groups or the withholding of certain therapies from a client;

(D) Except as provided in paragraph (b) of the preceding section ("Research That Needs To Be Reviewed *Only* By The Division"), research that requires the subject to respond to a questionnaire or survey;

(E) Research by Department employees for personal or academic reasons rather than as a part of their normal job duties in the Department.

VOLUNTEERS, INTERNS, OR INDIVIDUALS SERVING FIELD PRACTICUMS.

Volunteers, college and/or university students, interns, or individuals serving a field practicum with the Department are subject to this policy. Therefore, if such individuals plan to conduct research accessing or otherwise using DHS clients or client data, they must submit a proposal for applicable Human Rights Committee and/or Division review. If the volume of research from such individuals becomes too great for the Divisions and/or the Human Rights Committee to adequately process, the Divisions and/or the Committee reserve the right to deny these study requests based on administrative burden. If individuals are conducting literature reviews or presenting reports on topics related to their internship or practicum without using or accessing clients or client data, they are not subject to this policy.

TIMING FOR SUBMITTING PROPOSALS TO THE HUMAN RIGHTS COMMITTEE.

The Human Rights Committee meets monthly to review research proposals that affect the Department's clients or other human subjects related to the Department. All completed proposals received by the last day of the month will be reviewed during the second week of the following month. After reviewing the research proposals, the Committee submits a letter to the Department's Deputy Director, recommending either that the research proposal be given final approval or that the research proposal be denied.

INSTRUCTIONS FOR OBTAINING HUMAN RIGHTS APPROVAL.

If your proposed research requires approval from the Human Rights Committee, the researcher must complete the following steps:

1. **Letter of Support from the Division.** Contact the designated representative of the appropriate Division of the Department (see list below), and obtain a letter stating that the Division has reviewed the proposed research project and has determined that it is in the best interests of the Division and the Division's clients to approve the research proposal. (See the section above titled "Divisions as Gatekeepers in the Review Process" for the relevant criteria.) Submit this letter to the Human Rights Committee with the research proposal.

   Mary Caputo, M.P.A., Chair of Human Rights Committee,
   Bureau of Internal Review & Audit (BIRA) 538-4295
   Craig Bunker, J.D., Division of Substance Abuse (DSA) 538-4233
   Kelly Colopy, M.A., Office of Strategic Development (OSD) 538-4275
   John DeWitt, Ph.D., Division of Youth Corrections (DYC) 538-4330
   Sheldon B. Elman, M.P.A., Division of Aging & Adults Services (DAAS) 538-3921
   Caren Frost, Ph.D., Division of Child & Family Services (DCFS) 538-9856
   Dennis Geertsen, Ph.D., Division of Mental Health (DMH) 538-9879
   George Kelner, Ph.D., Division of Services for People with Disabilities (DSPD) 538-4208
   Jesse Soriano, M.A./M.S., Community Member 585-7012
   Kristin Urry, Division of Substance Abuse (DSA) 538-3952

2. **Letter of Support from Non-DHS Facility Administrator.** If subjects will be drawn from facilities which are not directly under the control of the above-listed Division or Agency, contact the administrator of each facility or program, and obtain a letter stating that: (a) the administrator is the person designated to review such proposal for the facility; and (b) the administrator has reviewed the proposed research project and has determined that it is in the best interests of the administrator's facility or program and in the best interests of the clients to approve the research proposal. Submit this letter to the Human Rights Committee as part of the research proposal.

3. **Research Agreement.** Review the attached Research Agreement, and submit a signed and dated copy of the Research Agreement to the Human Rights Committee as part of the research proposal.

4. **Research Proposal.** Complete the attached Research Proposal form **(including all information requested in Items 1 through 15)**, and submit the Research Proposal to the Human Rights Committee. The Research Proposal may be submitted in hard copy, by e-mail, or by a disk readable in WordPerfect or Microsoft Word.

5. **Cover Sheet for the Research Proposal.** Complete the attached Research Proposal cover sheet by providing the **necessary signatures** and relevant documents and submit it to:

Chairperson, Protection of Human Rights Review Committee
Utah Department of Human Services
c/o Executive Director's Office
120 North 200 West, Suite 319
Salt Lake City, Utah 84103

RESEARCH PROPOSAL COVER SHEET
UTAH STATE DEPARTMENT OF HUMAN SERVICES
Protection of Human Subjects Review Committee

Date of Proposal: _____
Name of Principal Investigator: _____
College/University or other Agency Affiliation: _____
Address: _____
City/State/Zip: _____
Work Phone: (____)_____ Home Phone: (____)_____
Anticipated Start Date: _____ End Date: _____

Is this study conducted by DHS employee(s)? ____Yes ____ No
Has the appropriate Division reviewed and approved the study? ____Yes ____No
Does this study involve the testing of drugs or biomedical devices? ____Yes ____No

1. TITLE AND NATURE OF STUDY:

2. RISK LEVEL (as defined in policy, page 4): ☐ Less than minimal risk; ☐ Minimal Risk; ☐ Greater than minimal risk but with direct benefit to subjects; ☐ Greater than minimal risk but no direct benefit to subjects. **(Briefly summarize the facts that support the risk level you have identified. If the study involves greater than minimal risk, identify all direct benefits to the human subjects as well as any additional safeguards.)**

3. PROTECTION OF RIGHTS AND WELFARE OF HUMAN SUBJECTS:
a. Review and support by Agency and Division (See "Instructions" in preceding section.):
_____Letter(s) of support from appropriate Division representative(s) attached.
_____Letter(s) of support from on-site administrator(s) attached.

b. Individual Information and Permission. Please attach the following documents:

YES	NO	N/A	ITEMS TO ATTACH TO THIS PROPOSAL
			1. Informational "recruitment statement" that the researcher will distribute to potential subjects.
			2. Informed-consent form that subjects must sign before they participate in the study.
			3. For children, or individuals who are legally incompetent, provide a sample letter requesting written permission of parent or legal guardian.
			4. Debriefing statement that researcher will distribute to the subjects after their participation is completed.
			5. Titles of any questionnaires, surveys or other instruments that the researcher will use in the study.
			6. Signed and dated Research Agreement form.

REQUIRED SIGNATURE

Principal Investigator: _____

ITEMS 1-15 ARE REQUIRED FOR ALL RESEARCH PROJECTS

Please Complete ALL of These Items. If an Item Does Not Apply, Indicate "N/A."

PROJECT DESCRIPTION

1. **Project Description.**

   (a) Briefly describe the objectives, methods and *general* procedures of the project. The emphasis should be on the human subject's involvement in the project. For example, describe any physiological or psychological intervention, the means used to administer the intervention, the behavior expected of the subject(s), and the behavior of the investigator during the intervention. Please avoid discussion of theoretical or statistical aspects of the project unless they relate to the protection of human subjects.

   (b) If questionnaires or testing instruments will be used, describe how they will be administered.

   (c) If interviews are to be conducted, describe the nature of the interview and how responses will be recorded.

   (d) The researcher may attach a copy of the project prospectus, if one is available.

2. **Outside IRB Review.** If this project is being reviewed by another human subjects research review group (e.g., a hospital institutional review board), attach a copy of the approval of that institution. If the review is still pending, include a statement of the current status of the pending review.

INFORMATION ABOUT THE HUMAN SUBJECTS INVOLVED IN PROJECT

3. **Subjects' Number and Characteristics.** Specify the number of the subjects and their relevant characteristics (e.g., police officers, students, random sample of nursing home patients).

4. **Remuneration.** Specify any remuneration that the researcher will give the subjects for their participation (e.g., money, gifts, free treatment). Please explain why this remuneration will not serve as a coercive influence or undermine the subjects' free, informed consent.

5. **Researcher's Relationship with Subjects.** Explain the relationship between the subject(s) and the researcher or investigator (e.g., students, clients, etc.). If there is no relationship prior to the research project, so state.

6. **Recruitment.** Explain how the researcher will identify and recruit the potential subject(s) for participation (e.g., random sample, subject pool). If recruitment involves the use of an intermediary recruiter (such as physicians recruiting their patients), please indicate whether the research is providing any remuneration to the intermediary recruiter (such as the physician), indicate the amount or value of the remuneration, and explain how or why this remuneration will not compromise the interests of the subject and unduly influence the intermediary recruiter's independent judgment about the best interests of the subject (such as the patient).

INFORMATION ABOUT RESEARCH RISKS AND BENEFITS AND RESEARCH PROTOCOLS

7. **Information about Risk/Benefit Analysis.**

a. Describe any risk(s), discomforts or consequences (either negative or positive) to the subject, and specify the level of risks to the subjects. (Risks, discomforts and consequences may be physical, psychological, or social.)

b. If the proposed study involves more than minimal risk to the subject, describe any benefit to the subject or others that outweighs this risk. (According to 45 CFR § 46.102 (i), "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")

c. Some research involves neither risks nor discomforts but rather violations of normal expectations. Specify whether the proposed study involves any such violations of normal expectations.

d. Describe the safeguards the researcher will take to minimize any potential risks, effects, or violations.

8. **Benefits to the Department.** Identify any potential benefit(s) that the research project will provide to the Utah Department of Human Services.

9. **Questionnaires, Tests, Interviews.** Attach copies of all questionnaires, testing instruments, or interview protocols. Include any cover letters or instructions that the researcher will provide to the subjects.

10. **Privacy and Confidentiality.**

a. Identify any personal identifiers or indicators (e.g., name, social security, etc.) that the researcher will record about each subject. (If none, so state.)

b. Explain the specific steps the researcher will take to safeguard the anonymity of the subjects or to protect the confidentiality of their responses.

c. Specify the procedures for the storage and ultimate disposal of personal information.

11. **Initial Client Contact.** The Department of Human Services cannot release clients' names or other identifying information without obtaining prior consent from each client. Explain how you will initially contact the clients to obtain their consent (e.g., arrange initial contact through a specific Department or Division representative.)

12. **Deception.** If ***deception*** is to be used in this project, explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigators.

13. **Debriefing the Research Subjects.** Describe in *detail* how the researcher will debrief the subjects. (If deception is used, debriefing is required unless the investigator articulates a compelling reason to delay or omit the debriefing.)

14. **Investigators' Qualifications.** Some research procedures may require a certain level of investigator competence and training. Please list the qualifications of each investigator, including the investigator's training, experience and relevant licensure.

15. **Drugs and Biomedical Devices**. Research procedures involving the investigation of new drugs, biomedical devices, or other special interventions require additional information and review. Please consult the Chairperson of the Human Rights Committee for details.

RESEARCH AGREEMENT

_____ (the "Researcher") is submitting a research proposal to the Utah Department of Human Services (the "Department"). The Researcher understands and agrees to the following terms and conditions:

- The Researcher has read and shall comply with the Department's informed-consent policies, which are set forth in Attachment "A" of this Research Agreement
- The Researcher shall use the research records only for the purposes stated in the application and approved by the Department.
- The Researcher shall assure the integrity, confidentiality, and security of the records. The Researcher shall take adequate steps to safeguard anonymity and protect the confidentiality of subjects during all phases of the research project.
- The Researcher shall not disclose any records in an individually-identifiable form except for the purpose of auditing or evaluating the research program or except as provided by the Utah Government Records and Management Act ("GRAMA"). The Researcher shall respect the Department's classification of its records, and shall comply with GRAMA and any other Utah statutes or regulations that allow or restrict public access to Department records.
- If the Department gives the Researcher access to Department records, the Researcher shall make no subsequent use or disclosure of those Department records without prior written authorization from the Department.
- The Researcher shall follow the procedures and methods described in the application and in any modifications made by the Department's Human Rights Committee.
- The Researcher shall notify the Department's Human Rights Committee immediately about any proposed changes in the research procedures or methods, and the Researcher shall not implement those changes unless the Committee approves them.
- The Researcher shall notify the Human Rights Committee immediately about any significant adverse reactions experienced by the subjects as a result of the study.
- The Researcher shall comply with the requirements of the Human Rights Committee and any institutional review boards of universities, colleges, hospitals or other institutions connected with the research.
- The Researcher shall comply with federal regulations about human-subjects research e.g., (45 CFR Part 46).
- If the Researcher's study involves elementary and secondary school students, the Researcher shall comply with the Utah Family Educational Rights and Privacy Act, *Utah Code Annotated* § 53A-13-301.
- The Researcher shall comply with all state and federal laws, including those that protect the privacy of individuals and research subjects. The Researcher understands that violation of any local, state, or federal law may subject the Researcher to criminal or civil prosecution or other penalties.

_____

Print name of Researcher's principal investigator

_____ Date: _____

Signature of Researcher's principal investigator

DHS INFORMED CONSENT POLICIES

Where informed consent is required, the Researcher shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. If the subject is a child or an adult with a legally authorized representative or guardian, but the subject is nevertheless capable of consenting to the research project, the Researcher must also obtain the informed assent of that child or adult. (As used in the following provisions of this policy, the term "subject" includes both the subject and the subject's legally authorized representative, if any.)

The Researcher shall give each subject a written informed-consent form that explains the study in simple, easily-understood language and easy-to-read type. The Researcher shall give each subject a reasonable opportunity to read the form and ask questions before signing the form.

At a minimum, the informed-consent form shall comply with the following requirements:

A. The informed-consent form shall not include any exculpatory language that requires or appears to require the subject to waive any of the subject's legal rights, nor may the form release or appear to release the Researcher, investigator, sponsor, the institution or their agents from liability for negligent or intentional harm.

B. The Researcher shall provide the subject with sufficient information and opportunity to consider whether or not to participate in the study.

C. The Researcher shall ensure that the possibility of coercion or undue influence is minimized.

D. The Researcher shall give the subject a written statement that clearly explains the following:

1. That the study involves research
2. The purposes of the research
3. How long the subject's participation will last
4. The procedures that the Researcher will use
5. Whether any of procedures the Researcher plans to use are experimental, and if so, which ones
6. The approximate number of subjects who will be involved in the study.
7. That participation in the research study is voluntary, and that refusal to participate in the study will not result in any penalty or loss of benefits to which the subject is otherwise entitled; and
8. That the subject may withdraw from the study at any time without penalty and without loss of any benefits to which the subject is otherwise entitled.

E. The Researcher shall give the subject a written description of any reasonably foreseeable risks, discomforts or consequences that the subject might experience as a result of participating in the study.

F. For research involving more than minimum risk, the Researcher shall give the subject a written explanation of:

1. Whether the subject may obtain compensation for any injuries or damages arising out of such risk;

2. Whether any medical treatment is available for such injuries or damages, and if so, what those treatments are and whether the Researcher will provided them free of charge to the subject; and

3. Whom the subject should contact to obtain further information about the risk of injury or damage or about compensation or treatment.

G. The Researcher shall give the subject a written description of any additional costs that the subject may incur as the result of participating in the research study.

H. The Researcher shall give the subject a written description of any benefits that the research project will provide to the subject or others.

I. The Researcher shall give the subject a written disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

J. If any of the Researcher's treatments or procedures pose currently unforeseeable risks to the subject or to an embryo or fetus if the subject becomes pregnant, the Researcher shall notify the subject in writing about this risk. (The Department will not approve any studies that involve foreseeable risk to a pregnant subject or to the subject's embryo or fetus.)

K. The Researcher shall give the subject a written statement describing the extent to which the Researcher will maintain confidentiality of records.

L. The Researcher shall notify the subject in writing whom the subject should contact if the subject has questions about the research or the subject's rights.

M. The Researcher shall give the subject a written statement listing the anticipated circumstances in which the Researcher may terminate the subject's participation in the research study.

N. The Researcher shall give the subject a written description of the consequences of a subject's decision to withdraw from the research study, and a description of the procedures for orderly termination of the subject's participation in the study.

O. The Researcher shall give the subject a written statement indicating that if the Researcher makes significant new research findings which relate to the subject's willingness to continue participation in the research project, the Researcher will notify the subject about those findings during the study.

P. The Researcher shall give the subject a written statement indicating that if the subject discloses any actual or suspected abuse, neglect or exploitation of a child, disabled adult or elder adult, the Researcher must report this abuse to the authorities, as required by federal and state laws.

Q. The Researcher shall give the subject a written statement indicating that if the subject discloses any other illegal acts, the Researcher may be required by state or federal laws to report certain illegal acts to the authorities.

R. If the subject is a child and the State has guardianship over the child, the Researcher shall give the subject a written statement indicating that the child is represented by the Office of the Guardian Ad Litem. To facilitate access to the Guardian Ad Litem, the statement shall also include the Guardian Ad Litem's phone number: (801) 578-3962.

Change, Ongoing, or Annual Resubmission of Research Proposal
UTAH DEPARTMENT OF HUMAN SERVICES
Protection of Human Rights Review Committee, Mary Caputo, Chairperson (801-538-4295)
120 North 200 West, Room 221, Salt Lake City, Utah 84103

Date of Report:_____ PHRRC #:_____
Researcher's Name:_____
Address:_____
Work Phone:_____ Home Phone:_____
Start Date: _____ Anticipated End Date: _____

NOTE: *All research projects must be reviewed by the Human Rights Committee no less than annually. If the Researcher plans to make* ***any*** *changes to the research design, instruments, or surveys, the Researcher must submit those changes for review, and obtain approval* ***before*** *the changes are implemented.*

1. **TITLE AND NATURE OF STUDY:**

2. **STUDY STATUS:** *(Check one)*

_____**NO CHANGES** have been made to the study protocol or instruments since the Human Rights Committee last approved the study.
Please provide an update of the study status including a copy of consent document used for most recent subject enrollment (see #3 below).

_____**CHANGES ARE PROPOSED** for the study protocol and instruments since the Human Rights Committee last approved the study.
Please attach a list that itemizes each change proposed for the protocol or instruments. Attach copies of all proposed protocol changes and all new or modified survey instruments or questionnaires. Include an update of the study status as requested #3 below.

_____**STUDY COMPLETED.**
Please attach a copy of the final report.

3. **UPDATE OF STUDY STATUS:** *(Please attach additional pages as necessary*)

4. **REQUIRED SIGNATURE:**

Principal Investigator:_____

Checklist for Division-Level Approval of Research Proposal
UTAH DEPARTMENT OF HUMAN SERVICES

(This form may be used as the Division's Letter of Support of a Research Proposal being submitted for Human Rights Committee review and/or may be used for Division approval of research only requiring only Division review and approval.) If a study involves more than minimal risk and no direct benefit to the subject, attach a separate justification statement. ***A copy of the completed form must also go to the Human Rights Committee Chair.***

Date of Review:_____
Researcher's Name:_____
Address:_____
Work Phone:_____ Home Phone:_____
Start Date: _____ Anticipated End Date: _____

1. TITLE AND NATURE OF STUDY:

2. REVIEWED FOR THE FOLLOWING:

_____(a) the research is in the best interests of the Division and the Division's clients;

_____(b) the researcher has made adequate provision for obtaining all required informed consents and informed assents;

_____(c) the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the researcher's gathering of the data, storage and retrieval of the data, and publication of the data;

_____(d) the research study involves no more than minimal risk* to subjects, or the direct benefits to the subjects outweigh the risks;

_____(e) the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department or the Division; and

_____(f) the research protocol protects individual privacy rights and complies with the Department's Vision and Mission Statements, the Department Code of Ethics and any applicable rules or statutes, including UCA § 63-2-202 (8).

3. RECOMMENDATION FOR APPROVAL: Yes _____ No _____

Division Representative: _____ Date: _____

Division Director: _____ Date: _____

_____

[1] According to 45 CFR § 46.102 (i), "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

APPENDIX A

Definitions of The Terms "Phase I Study," "Phase II Study" and "Phase III Study"

As used in these policies and procedures on "Protecting the Rights of Human Research Subjects," the terms "Phase I Study," "Phase II Study," and "Phase III Study" have the following meanings, which are taken from definitions in the Code of Federal Regulations:

Phase I Study: A "Phase I study" refers to the initial introduction of an investigational new drug into humans. Phase I studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase I, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase II studies. The total number of subjects and patients included in Phase I studies varies with the drug, but is generally in the range of 20 to 80. Phase I studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase II Study: The term "Phase II study" refers to controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase II studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.

Phase III Study: "Phase III studies" are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III studies usually include from several hundred to several thousand subjects.

See 21 C.F.R. . 312.21.

NOTE: The Utah Department of Human Services does *not* approve Phase I studies or Phase II studies.